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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 10/056,417 | 01/24/2002 | Kevin Tingey | P-5243 | 8066 |

26253 7590 04/15/2004

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| EXAMINER |
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MCAVOY, ELLEN M

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| ART UNIT | PAPER NUMBER |
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1764

DATE MAILED: 04/15/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/056,417

Applicant(s)

TINGEY ET AL.

Examiner

Ellen M McAvoy

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-20 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 24 January 2002 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date <u>2/19/2003</u> . | 6) <input type="checkbox"/> Other: ____ |

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1 and 4-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Igarashi et al (EP 716,834 A1).

Igarashi et al ["Igarashi"] disclose a stent for intracorporeal retention which has a hollow cylindrical body and an internal surface which may be processed by chemical deposition of polyparaxylylene or a derivative thereof, or a fluorine based resin. See the claims. The examiner is of the position that Igarashi meets the limitations of the above rejected claims when the medical device is a stent.

Claim Rejections - 35 USC § 103

Claims 1-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Goldhardt et al (WO 95/04564) and Ragheb et al (WO 00/10622), considered separately.

Goldhardt et al ["Goldhardt"] disclose an external feeding device which may be coated on both the outer and inner surfaces by a poly(p-xylene) polymer (parylene). See page 6, last paragraph. Goldhardt teaches that the poly(p-xylene) polymers are well-known and that coating onto an outer and/or inner wall of a tubular member may be carried out by a vapor deposition process. See page 7, line 1 to page 8, top. Although a thickness of the lay is not set forth by the

prior art, Goldhardt teaches that the coating thickness is relatively uniform with excellent conformity. Goldhardt also teaches that parylene has been used to coat other medical devices such as orthopedic products to render their materials compatible with body tissue and to serve as a dry film lubricant. Thus, the examiner is of the position that it would be obvious to coat all such medical devices if compatibility with body tissue and lubrication are so desired.

Ragheb et al ["Ragheb"] disclose a coated implantable medical device which comprises a porous layer including a polymer applied by vapor or plasma deposition. The polymer may be a parylene or parylene derivative and the coating thickness is about 5,000 to 250,000 Angstroms (A), which converts to about 0.5 to 25 microns. See page 5, last paragraph, to page 6. Ragheb teaches that "parylene" is a generic name for a known group of polymers based on p-xylylene and made by vapor phase polymerization, and that such parylene coatings applicable by vapor deposition are known for a variety of biomedical uses. Applicants' open-ended claim language "comprising" allows for the addition of other layers or coatings such as those taught in Ragheb.

Conclusion

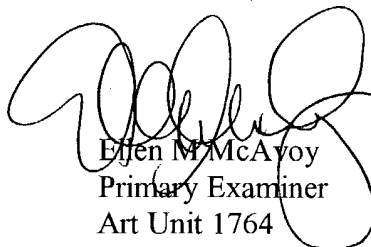
The prior art made of record and not relied upon is considered pertinent to applicants' disclosure.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ellen M McAvoy whose telephone number is (571) 272-1451. The examiner can normally be reached on M-F (7:30-5:00) with alt. Fridays off.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Glenn Caldarola can be reached on (571) 272-1444. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Ejen M. McAvoy
Primary Examiner
Art Unit 1764

EMcAvoy
April 13, 2004